K111694

510(k) Summary of Safety

SEP 15 2011

This 510(k) summary of safety information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Date Prepared:

May 17, 2011

Submitters Information: 21 CFR 807.92(a)(1)

Mr. Vincent Cipolla
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Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2)

Trade Name: ASTRA
Common name: Picture Archiving Communications System
Classification Name: 892.2050 Image Processing System
Product Code: LLZ

Predicate Device(s): 21 CFR 807.92(a)(3)

510(k) Number	K092949	K103785
Manufacturer:	Candelis, Inc.	MIM Software, Inc
Device Name:	ImageGrid Radiology Viewer	Mobile MIM
Decision Date:	10/08/2009	2/4/2011
Product Code:	LLZ	LLZ
Device Classification Name:	System, Image Processing, Radiological	System, Image Processing, Radiological
Regulation Number:	Class II – 892.2050	Class II – 892.2050
Reviewed by Third Party:	Yes	No

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Device Description: 21 CFR 807.92(a)(4)

ASTRA is a web-enabled software application that provides image processing and viewing tools and access to studies and reports from a Local Area Network, Wide Area Network, remote workstation, personal computer, or an iPhone, or iPad via a Virtual Private Network connection. Diagnosis is not performed by the software but by Radiologists, Clinicians or referring Physicians. The software application conforms to the DICOM 3.0 standard to allow interoperability with other DICOM compliant systems.

Indications for Use: 21 CFR 807.92(a)(5)

ASTRA is software image management intended to receive, process, review, display, print and archive medical images and data from imaging modalities (e.g., CR and DR). Images and data can be stored, communicated, and displayed within the system or across computer systems. ASTRA is comprised with three configurations depending upon the requirements of the user and desired options: ASTRA Plus , ASTRA Lite, and ASTRA Mobile. ASTRA runs on a PC workstation, iPad, or iPhone and may be interfaced with verified and validated image acquisition devices from Candelis or other PACS systems. Diagnosis is not performed by the software but by Radiologists, Clinicians or referring Physicians. Typical users of this system are trained professionals, e.g. physicians, radiologists, nurses, medical technicians, and assistants.

ASTRA Plus is used to:

- share reports and studies with other ASTRA peers
- review reports and studies
- download and save reports
- send reports to local EMR, EHR, RIS, HIS or PACS systems (HL7 send)
- route studies to PACS, Workstations, or other ASTRA peers

ASTRA Lite is used to:

- share reports and studies with other ASTRA peers
- review reports and studies
- download and save reports
- send reports to local EMR, EHR, RIS, HIS or PACS systems (HL7 send)

ASTRA Mobile is used to:

- share reports with other ASTRA peers
- review reports
- download and save reports
- send reports to local EMR, EHR, RIS, HIS or PACS systems (HL7 send)

Only pre-processed DICOM for presentation images can be interpreted for primary image diagnosis in mammography. Lossy compressed Mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 Megapixel resolution and meets other technical specifications reviewed and accepted by FDA.

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Technological Characteristics: 21 CFR 807.92(a)(6)

ASTRA is a software product that handles digital medical images and reports. The device does not contact the patient, nor does it control any life sustaining devices. A physician, providing ample opportunity for competent human intervention interprets images and information being displayed and printed.

Testing:

The complete system configuration has been assessed and tested at the factory and the device has passed all in-house testing criteria without significant failures. The data presented in the submission demonstrates that the ASTRA device performs all required actions according to the functional requirements specified in the SRS and User Manual with no errors that had an impact on safety or efficacy.

Conclusion: 21 CFR 807.92(b)(1)

The 510 (k) Pre-Market Notification for Candelis ASTRA contains adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate device. ASTRA has been and will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey. The submission contains the results of a hazard analysis and the "Level of Concern for potential hazards has been classified as "Moderate".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Vincent Cipolla
Manager Quality/Regulatory Compliance
Candelis, Inc.
18821 Bardeen Avenue
IRVINE CA 92612

SEP 15 2011

Re: K111694
Trade/Device Name: ASTRA
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 31, 2011
Received: August 31, 2011

Dear Mr. Cipolla:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

CANDELIS

Indications for Use Statement

510(k) Number (if known):

Device Name: ASTRA

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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